

ANDROBALANCE- dhea (dehydroepiandrosterone) pregnenolone, progesterone, testosterone spray
BioActive Nutritional, Inc.

Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.

Drug Facts:

ACTIVE INGREDIENTS:

DHEA (Dehydroepiandrosterone) 6X, Pregnenolone 8X, Progesterone 8X, Testosterone 8X.

INDICATIONS:

For temporary relief of symptoms due to male andropause such as: lethargy, muscle weakness and aches, and decrease in libido.

WARNINGS:

If pregnant or breast-feeding, ask a health care professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Do not use if tamper evident seal is broken or missing.

Store in cool, dry place.

KEEP OUT OF REACH OF CHILDREN:

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

DIRECTIONS:

One spray three times per day. Hold in mouth for two minutes.

INDICATIONS:

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INACTIVE INGREDIENTS:

Citric Acid, Demineralized water, Glycerin, Sodium benzoate.

QUESTIONS:

Distributed by:
BioActive Nutritional, Inc.
1803 N. Wickham Rd.
Melbourne, FL 32935

PACKAGE LABEL DISPLAY:

BIOActive Nutritional

ANDROBALANCE

HOMEOPATHIC

1 FL OZ (30 ml)



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LOT:

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BioActive Nutritional, Inc.
1803 N. Wickham Rd.
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bioactivenutritional.com

ANDROBALANCE

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| Product Information | | | |
|------------------------------------------------------------------|----------------|--------------------|------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:43857-0284 |
| Route of Administration | ORAL | | |
| | | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| PRASTERONE (UNII: 459AG36T1B) (PRASTERONE - UNII:459AG36T1B) | | PRASTERONE | 6 [hp_X] in 1 mL |
| PREGNENOLONE (UNII: 73R90F7MQ8) (PREGNENOLONE - UNII:73R90F7MQ8) | | PREGNENOLONE | 8 [hp_X] in 1 mL |
| PROGESTERONE (UNII: 4G7DS2Q64Y) (PROGESTERONE - UNII:4G7DS2Q64Y) | | PROGESTERONE | 8 [hp_X] in 1 mL |
| TESTOSTERONE (UNII: 3XMK78S47O) (TESTOSTERONE - UNII:3XMK78S47O) | | TESTOSTERONE | 8 [hp_X] in 1 mL |
| | | | |
| Inactive Ingredients | | | |
| Ingredient Name | | | Strength |
| GLYCERIN (UNII: PDC6A3C0OX) | | | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | | | |

| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | | | | |
|--------------------------------------------|------------------|-------------------------------------------------------------|----------------------|--------------------|
| WATER (UNII: 059QF0KO0R) | | | | |
| | | | | |
| Packaging | | | | |
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:43857-0284-1 | 30 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product | 04/13/2017 | |
| | | | | |
| Marketing Information | | | | |
| Marketing Category | | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved homeopathic | | | 02/24/2014 | |
| | | | | |

Labeler - BioActive Nutritional, Inc. (624980496)

Registrant - Apotheca Company (844330915)

| Establishment | | | |
|----------------------|---------|-----------|----------------------------------------------------------------------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Apotheca Company | | 844330915 | manufacture(43857-0284) , api manufacture(43857-0284) , label(43857-0284) , pack(43857-0284) |